UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,905	11/13/2003	Charles R. Stomberg	P-20003.00	9463

27581   7590   12/11/2006

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EXAMINER
LUSTUSKY, SARA

ART UNIT	PAPER NUMBER
3735	

DATE MAILED: 12/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

	Application No.	Applicant(s)
Office Action Summary	10/712,905	STOMBERG ET AL.
	Examiner	Art Unit	
	Sara Lustusky	3735	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**.   2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2,4-11,13-20,22-23* is/are rejected.

7)☒ Claim(s) *3,12,21* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on <u>13 November 2003</u> is/are: a)☐ accepted or b)☒ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All   b)☐ Some * c)☐ None of:

      1.☐ Certified copies of the priority documents have been received.

      2.☐ Certified copies of the priority documents have been received in Application No. _____.

      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>11/13/03, 5/11/05</u>.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application

6)☐ Other: _____.

DETAILED ACTION

Drawings

1.   The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: (11) as seen in Figure 1, (600) as seen in Figure 6, (760) as seen in Figure 7, (800) as seen in Figure 8, (835) as seen in Figure 9 and (895) as seen in Figure 10. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

2.   **Claim 10** is objected to because of the following informalities:

3.   The recitation "corrected data correlated to" in line 8 should read - - corrected data correlates to - -. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4.   The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that

form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5.   **Claims 10-11** are rejected under 35 U.S.C. 102(b) as being anticipated by

Aoyama et al. (US 5921938 A).

6.   Aoyama et al. teaches an apparatus comprising:

    a.   communication means capable of communicating with and receiving time

data from an implantable medical device, measuring means capable of

determining an amount of drift or lost time in the time data relative to a reference

time, and correction means capable of correcting the data by removing the drift,

which may be a positive or negative time difference, so that the corrected data

correlates to the reference time (as described in lines 1-12 of the abstract and in

claims 1-2, 5, 6, 8, 10, 12-13, 15 and 26).

7.   **Claims 10 and 14** are rejected under 35 U.S.C. 102(b) as being anticipated by

MacDuff et al. (US 6041257 A).

8.   MacDuff et al. teaches an apparatus comprising:

    a.   communication means capable of communicating with and receiving time

data from an implantable medical device, measuring means capable of

determining an amount of drift or lost time in the time data relative to a reference

time, and correction means capable of correcting the data by removing the drift

or lost time so that the corrected data correlates to the reference time (as

described in lines 45-62 of column 3 and in lines 17-34 and 41-45 of column 6);

wherein the apparatus is capable of simultaneously synchronizing time data from

multiple implantable medical device to the reference time (as described in lines

20-22 of column 13 and in lines 8-21 of column 14).

Claim Rejections - 35 USC § 103

9.   The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set
> forth in section 102 of this title, if the differences between the subject matter sought to be patented and ·
> the prior art are such that the subject matter as a whole would have been obvious at the time the
> invention was made to a person having ordinary skill in the art to which said subject matter pertains.
> Patentability shall not be negatived by the manner in which the invention was made.

10.   **Claims 1-2, 4-9, 13, 15-16, 18-20 and 22-23** are rejected under 35 U.S.C. 103(a)

as being unpatentable over Aoyama et al. (US 5921938 A) in view of Goedeke (US

5904708 A).

11.   Aoyama et al. teaches a method comprising:

a.   detecting a first time output from the clock of an implantable medical

device at a first time, detecting a first time output from a reference clock at the

first time; detecting a second time output from the clock of the implantable

medical device at a second time, detecting a second time output from the

reference clock; and calculating the drift based on the difference between the

second time output from the clock of the implantable medical device and the

second time output from the reference clock (as described in claims 1-2, 5, 6, 8,

10-16 and 26);

b.   generating a correction factor to correct for the drift and correlating time

data from the clock to a reference time frame by correcting for the drift (as

described in lines 6-21 of column 7 and in lines 42-45 of column 8 describing an

alternate embodiment);

c.   wherein the time data is received at a programmer and then correlated (as

described in lines 25-37 of column 7);

d.   programming the implantable medical device with the correction factor (as

described in claims 5, 8 and 11);

e.   wherein identifying lost time includes identifying periods of therapy

delivery (as described in lines 40-45 of column 1 and in lines 9-15 of column 8);

f.   wherein correcting includes modifying data from the implantable medical

device with a positive or negative time difference so that time is added or

subtracted from the data temporally proximate wherein the time was lost or

gained (as seen in Figures 2B and 3);

g.   wherein the method instructions are contained on a computer readable

medium that when executed on an electronic device, causes the electronic

device to perform functions according to the instructions (as described in lines 1-

63 of column 4 and in lines 26-34 of column 5);

h.   wherein the programmer comprises a communication link

communicatively coupleable to a medical device capable of receiving time data

from the device, a reference clock providing reference time data, and a

calibrating module that receives the device time data and the reference time

data, measures drift in the device data and generates a correction factor (as

described in lines 6-20 and 31-44 of column 7); and

i.   wherein the calibrating module is operatively coupled with the

communication link so that the correction factor is programmed into the device,

wherein the correction factor may be determined by an algorithm indicating a

positive or negative time difference (as described in claims 1-2, 5, 6, 8, 10, 12-

13, 15 and 26).

12.   While Aoyama et al. teaches that the medical device may be a defibrillator or a

monitor having a clock, implantable devices are not expressly taught nor is it expressly

taught that the clock is an oscillator.

13.   Goedeke teaches time synchronization of a clock (138) of an implantable medical

device (100) with an external reference clock (as described in lines 52-62 of column 9),

wherein the implantable medical device (100) may be a defibrillator (as described by the

embodiment in lines 19-26 of column 1). Goedeke further teaches that the clock (138) of

the implantable device (100) is an oscillator (138) (as described in lines 28-29 of column

10) (as seen in Figures 1 and 2) connected to a circuit having a programming means for

correlating the frequency to a standard time format (as described in lines 49-65 of

column 10).

14.   It would have been obvious to one of ordinary skill in the art at the time of the

invention to use a method similar to that of Aoyama et al. to synchronize the clock of an

implantable medical device similar to the method of Goedeke in order to ensure that the

data received from the implantable medical device accurately reflects the sequence of

treatment or use of the implantable medical device which directly reflects and/or

indicates the health of the patient. Furthermore, electronic clocks comprising crystals or

oscillators were commonly used in implantable devices at the time of the invention.

15.   **Claims 15 and 17** are rejected under 35 U.S.C. 103(a) as being unpatentable

over MacDuff et al. (US 6041257 A) in view of Goedeke (US 5904708 A).

16.   MacDuff et al. teaches an programmer comprising:

a.   a communication link communicatively coupleable to an implantable

medical device capable of receiving time data from the implantable medical

device, a reference clock, measuring means capable of determining an amount

of drift or lost time in the time data relative to the reference clock time, and a

calibrating module that receives the implantable medical device time data and

the reference time data, wherein the programmer generates a correction factor

(as described in lines 45-62 of column 3 and in lines 17-34 and 41-45 of column

6);

b.   wherein the calibrating module measures drift based on an algorithm that

determines a slope of a divergence between the implantable medical device time

data and the reference data (as described in columns 9 and 10) (as seen in

Figures 7-13).

17.   While MacDuff et al. teaches that the medical device may be a device such as a

defibrillator (as described in lines 22-25 of column 13), implantable devices are not

expressly taught.

18.   Goedeke teaches time synchronization of a clock (138) of an implantable medical

device (100) with an external reference clock (as described in lines 52-62 of column 9),

wherein the implantable medical device (100) is a defibrillator (as described by the

embodiment in lines 19-26 of column 1).

19. It would have been obvious to one of ordinary skill in the art at the time of the invention to use a method similar to that of MacDuff et al. to synchronize the clock of an implantable medical device similar to the method of Goedeke in order to ensure that the data received from the implantable medical device accurately reflects the sequence of treatment or use of the implantable medical device which directly reflects and/or indicates the health of the patient.

Allowable Subject Matter

20. **Claims 3, 12 and 21** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

21. Regarding claims 3 and 21, none of the prior art of record teaches or fairly suggests a method or a computer readable medium containing instructions for the executable method comprising measuring drift of a clock within an implantable medical device and generating a correction factor to correct for the drift; wherein measuring comprises detecting a first and second time output from the clock of the implantable medical device at a first and second time, respectively, and detecting a first and second time output from a reference clock at the same first and second respective times; and calculating the drift by determining a slope of a divergence between a first timeline defined between the first and second time for the clock of the implantable medical device and a second timeline defined between the first and second time for the reference clock.

22.   Regarding claim 12, none of the prior art of record teaches or fairly suggests an apparatus for correlating time data from an implantable medical device comprising communication means, measuring means, correction means, and means for determining differences between the time data and the reference time due to time zone variations and means for modifying the time data to eliminate the difference due to time zone variations.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Osorio et al. (US 2004/0133390 A1), Mazar (US 2004/0116981 A1) and Frei et al. (US 2004/0152958 A1) teach methods of analyzing transmitted times of medical devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sara Lustusky whose telephone number is (571) 272 8965. The examiner can normally be reached on M-F: 9 - 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on (571) 272 4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the

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published applications may be obtained from either Private PAIR or Public PAIR.

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USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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S.L.